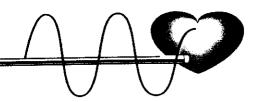
# FLOWCARDIA, INC.



### 510(k) Summary of Safety and Effectiveness

Ko51062

Application Date:

April 25, 2005

JUL 1 5 2005

Submission Type:

510(k), Traditional

**Applicant** 

FlowCardia, Inc. (Owner) 745 N. Pastoria Avenue

Manufacturing Address:

Sunnyvale, CA 94085

Ph: (408) 617-0352, Fx: (408) 617-9198

Contact person: Richard Spano

Establishment

3005007189

Registration:

(Same as above)

Device Common Name:

Guidewire

Device Trade Name:

VP Wire GW140ST (.014" 165cm, Standard)

VP Wire GW140SO (.014" 165cm, Soft)

VP Wire GW143ST (.014" 300cm, Standard)

VP Wire GW143SO (.014" 300cm, Soft)

Device

Class II (21CFR 870.1330), CDRH Code DQX,

Classification:

Cardiovascular Panel

Reason for 510(k):

**New Device Submission** 

Substantially

K022762 (original), K031277 (special), K032615

equivalent to:

(special) Asahi Wire, product code: DQX

K990639 CROSS IT 300XT, product code: DQX

Contact Sterilizer:

Nutek Corporation (Reg. No. 2950103)

30958 San Antonio St Hayward, CA 94544

Special Controls:

No applicable mandatory performance standards or

special controls exist for this device.

745 North Pastoria Avenue, Sunnyvale, CA 94085-2918 Phone: (408) 617-0352 Fax (408) 617-9198

### **Device Description**

The FlowCardia VP Wire is a steerable guide wire with an outer diameter of 0.014" and available in 165 cm or 300 cm overall length. They are constructed from a stainless steel core wire with varying core and coil lengths for each design. The proximal end of the core wire is coated with polytetrfluoroethylene (PTFE). A short radiopaque coil tip is soldered to the distal end of the core wire.

#### Intended Use

The VP Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

### Technological Characteristics as Compared to Predicate Device:

The FlowCardia VP Wires are constructed from the same materials, offered in the same lengths and diameters, have the same designs and indications for use as the predicate devices and other PTCA Guide Wires that are currently on the market.

### Performance Data:

Animal, Bench, and Biocompatibility testing was conducted according to the relevant guidance documents to demonstrate that the FlowCardia VP Guide Wires met the acceptance criteria and performed similarly to the predicate devices. The following functional tests were performed: Tensile Strength, Torque Strength, Torqueability, Tip Flexibility, Coating Adherence/integrity, Biocompatibility, and Catheter Compatibility. No new safety or effectiveness issues were raised during the testing.

#### Conclusion:

The FlowCardia VP Guide Wires are substantially equivalent to the claimed predicates devices and other currently marketed PTCA Guide Wires.

Premarket	Notification	[510(k)]	Number	





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUL 1 5 2005

Flowcardia, Inc. c/o Mr. Richard Spano Vice President, Operations and Quality 745 North Pastoria Avenue Sunnyvale, CA 94085-2918

Re:

K051062

Trade/Device Name: FlowCardia VP Wires Regulation Number: 21 CFR 870.1330 Regulation Name: Catheter Guide Wire

Regulatory Class: Class II Product Code: DQX Dated: April 25, 2005 Received: May 3, 2005

Dear Mr. Spano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21)

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>.

Sincerely yours,

orma R. Victimes

Bram D. Zuckerman, M.D. Director

Division of Cardiovascular Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

## Statement of Indications for Use

510(k) Number (if known): **Ko51062** 

Device Name: FlowCardia VP Wires

### Indications for Use:

The VP Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

Prescription UseX (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use(21 CFR 801 Subpart C)
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NEEDED)		
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number <u>K051062</u>